

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CAI *et al.*Appl. No.: 10/510,104 (U.S. Nat'l Phase of  
PCT/US2003/10645)

Int'l Filing Date: April 7, 2003

Confirmation No.: *To be assigned*Art Unit: *To be assigned*Examiner: *To be assigned*

Atty. Docket: 1735.0760002/RWE/RAS

**For: Caspase Inhibitors for the Treatment of  
Diseases and Conditions Caused by  
Exposure to Radionuclides, Biological  
Agents, or Chemical Agents**

**Information Disclosure Statement  
under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents AL1-AS14 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached Form PTO-1449 are submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants note that the month of publication could not be determined for document AT9. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert A. Schwartzman, Ph.D.  
Agent for Applicants  
Registration No. 50,211

Date: April 5, 2005

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354909v1

FORM PTO-1449

**INFORMATION DISCLOSURE STATEMENT**

ATTY. DOCKET NO.  
1735.0760002/RWE/RAS

APPLICATION NO.  
10/510,104 (U.S. Nat'l Phase of  
PCT/US03/10645, filed April 7, 2003)

APPLICANT(S)  
Cai *et al.*

35 U.S.C. § 3 71 DATE  
October 5, 2004

ART UNIT  
To be assigned

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	6,153,591	11/28/2000	Cai <i>et al.</i>			03/16/1999
	AB1	6,355,618 B1	03/12/2002	Cai <i>et al.</i>			04/07/2000
	AC1	6,495,522 B1	12/17/2002	Wang <i>et al.</i>			08/28/2000
	AD	6,566,338 B1	05/20/2003	Weber <i>et al.</i>			10/11/2000
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 01/27140 A1	04/19/2001	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	1	Abstract of Allam, M., <i>et al.</i> , "Cholera toxin triggers apoptosis in human lung cancer cell lines," <i>Cancer Res.</i> 57:2615-2618, American Association for Cancer Research (1997)
	AS	1	Abstract of Ardelt, B., <i>et al.</i> , "Chlorophyllin protects cells from the cytostatic and cytotoxic effects of quinacrine mustard but not of nitrogen mustard," <i>Int. J. Oncol.</i> 18:849-853, D.A. Spandidos (April 2001)
	AT	1	Abstract of Baize, S., <i>et al.</i> , "Apoptosis in fatal Ebola infection. Does the virus toll the bell for immune system?" <i>Apoptosis</i> 5:5-7, Kluwer Academic Publishers (2000)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>2</u>	Abstract of Baize, S., <i>et al.</i> , "Defective humoral responses and extensive intravascular apoptosis are associated with fatal outcome in Ebola virus-infected patients," <i>Nat. Med.</i> 5:423-426, Nature Publishing Company (1999)
	AS	<u>2</u>	Abstract of Braun, J.S., <i>et al.</i> , "Apoptosis-inducing factor mediates microglial and neuronal apoptosis caused by pneumococcus," <i>J. Infect. Dis.</i> 184:1300-1309, University of Chicago Press (November 2001)
	AT	<u>2</u>	Abstract of Brito, G.A., <i>et al.</i> , "Mechanism of Clostridium difficile toxin A-induced apoptosis in T84 cells," <i>J. Infect. Dis.</i> 186:1438-1447, University of Chicago Press (November 2002)

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	AR	<u>3</u>	Abstract of Buratta, S., <i>et al.</i> , "Group B streptococcus (GBS) modifies macrophage phosphatidylserine metabolism during induction of apoptosis," <i>FEBS Lett</i> 520:68-72, Elsevier Science B.V (June 2002)
	AS	<u>3</u>	Abstract of Doggweiler, R., <i>et al.</i> , "Botox-induced prostatic involution," <i>Prostate</i> 37:44-50, Wiley-Liss (1998)
	AT	<u>3</u>	Abstract of Gan, Y.H., <i>et al.</i> , "Molecular mechanism of apoptosis induced by ricin in HeLa cells," <i>Acta Pharmacol. Sin.</i> 21:243-248, Blackwell Publishing (2000)

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	AR	4	Abstract of Geisbert, T.W., <i>et al.</i> , "Apoptosis induced in vitro and in vivo during infection by Ebola and Marburg viruses," <i>Lab. Invest.</i> 80:171-186, Lippincott Williams & Wilkins (2000)
	AS	4	Abstract of Grinberg, L.M., <i>et al.</i> , "Quantitative pathology of inhalational anthrax I: quantitative microscopic findings," <i>Mod. Pathol.</i> 14:482-495, Lippincott Williams & Wilkins (May 2001)
	AT	4	Abstract of Hasegawa, N., <i>et al.</i> , "Isolated ricin B-chain-mediated apoptosis in U937 cells," <i>Biosci. Biotechnol. Biochem.</i> 64:1422-1429, Japan Society for Bioscience, Biotechnology, and Agrochemistry (2000)

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	AR	5	Abstract of Hu, R., <i>et al.</i> , "An insight into the mechanism of cytotoxicity of ricin to hepatoma cell: roles of Bcl-2 family proteins, caspases, Ca(2+)-dependent proteases and protein kinase C," <i>J. Cell. Biochem.</i> 81:583-593, Liss (March-April 2001)
	AS	5	Abstract of Kerro Dego, O., <i>et al.</i> , "Factors involved in the early pathogenesis of bovine Staphylococcus aureus mastitis with emphasis on bacterial adhesion and invasion. A review," <i>Vet. Q</i> 24:181-198, Euroscience (December 2002)
	AT	5	Abstract of Komatsu, N., <i>et al.</i> , "Involvement of both caspase-like proteases and serine proteases in apoptotic cell death induced by ricin, modeccin, diphtheria toxin, and pseudomonas toxin," <i>J. Biochem (Tokyo)</i> 124:1038-1044, Oxford University Press for Japanese Biochemical Society (1998)

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	AR	<u>10</u>	Abstract of Qa'Dan, M., <i>et al.</i> , "Clostridium difficile toxin B activates dual caspase-dependent and caspase-independent apoptosis in intoxicated cells," <i>Cell. Microbiol.</i> 4:425-434, Blackwell Science (July 2002)
	AS	<u>10</u>	Abstract of Rohrbach, S., <i>et al.</i> , "Botulinum toxin type A induces apoptosis in nasal glands of guinea pigs," <i>Ann. Otol. Rhinol. Laryngol.</i> 110:1045-1150, Annals Publishing Co (November 2001)
	AT	<u>10</u>	Abstract of Sun, X.M., <i>et al.</i> , "Effects of sterigmatocystin, deoxynivalenol and aflatoxin G1 on apoptosis of human peripheral blood lymphocytes in vitro," <i>Biomed. Environ. Sci.</i> 15:145-152, Academic Press (June 2002)

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	AR	2	Abstract of Popov, S.G., <i>et al.</i> , "Effect of Bacillus anthracis lethal toxin on human peripheral blood mononuclear cells," <i>FEBS Lett.</i> 527:211-215, Elsevier Science B.V. (September 2002)
	AS	2	Abstract of Popov, S.G., <i>et al.</i> , "Lethal toxin of Bacillus anthracis causes apoptosis of macrophages," <i>Biochem. Biophys. Res. Commun.</i> 293:349-355, Academic Press (April 2002)
	AT	2	Abstract of Pozzi, C.R., <i>et al.</i> , "Effects of prolonged oral administration of fumonisin B1 and aflatoxin B1 in rats," <i>Mycopathologia</i> 151:21-27, Kluwer Academic (2001)

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AR	8	Abstract of Park, J.M., <i>et al.</i> , "Macrophage apoptosis by anthrax lethal factor through p38 MAP kinase inhibition," <i>Science</i> 297:2048-2051, American Association for the Advancement of Science (September 2002)
AS	8	Abstract of Pette, M., <i>et al.</i> , "Mafosfamide induces DNA fragmentation and apoptosis in human T-lymphocytes. A possible mechanism of its immunosuppressive action," <i>Immunopharmacology</i> 30:59-69, Elsevier/North-Holland (1995)
AT	8	Abstract of Pitman, R.S., <i>et al.</i> , "Receptor mediated apoptosis of CD8+T cells by the B subunits of cholera-like enterotoxins," <i>Biochem. Soc. Trans.</i> 26:S338, Portland Press On The Behalf Of The Biochemical Society (1998)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	7	Abstract of Meli, D.N., <i>et al.</i> , "Current concepts in the pathogenesis of meningitis caused by <i>Streptococcus pneumoniae</i> ," <i>Curr. Opin. Infect. Dis.</i> 15:253-257, Lippincott Williams & Wilkins (June 2002)
	AS	7	Abstract of Mempel, M., <i>et al.</i> , "Invasion of human keratinocytes by <i>Staphylococcus aureus</i> and intracellular bacterial persistence represent haemolysin-independent virulence mechanisms that are followed by features of necrotic and apoptotic keratinocyte cell death," <i>Br. J. Dermatol.</i> 146:943-951, Blackwell Scientific Publications (June 2002)
	AT	7	Abstract of Nakagawa, I., <i>et al.</i> , "Cytochrome c-mediated caspase-9 activation triggers apoptosis in <i>Streptococcus pyogenes</i> -infected epithelial cells," <i>Cell. Microbiol.</i> 3:395-405, Blackwell Science (June 2001)

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	AR	<u>6</u>	Abstract of Li, L., <i>et al.</i> , "Oxidative stress and cyclooxygenase-2 induction mediate cyanide-induced apoptosis of cortical cells," <i>Toxicol. Appl. Pharmacol.</i> 185:55-63, Academic Press (November 2002)
	AS	<u>6</u>	Abstract of Lin, C.G., <i>et al.</i> , "Cytotoxic effects of anthrax lethal toxin on macrophage-like cell line J774A.1," <i>Curr. Microbiol.</i> 33:224-227, Springer International (1996)
	AT	<u>6</u>	Abstract of Meki, A.R., <i>et al.</i> , "Aflatoxin B1 induces apoptosis in rat liver: protective effect of melatonin," <i>Neuro. Endocrinol. Lett.</i> 22:417-426, Society of Integrated Sciences (December 2001)

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	AR	<u>11</u>	Abstract of Weeks, S., <i>et al.</i> , "Anti-V antigen antibody protects macrophages from Yersinia pestis-induced cell death and promotes phagocytosis," <i>Microb. Pathog.</i> 32:227-237, Academic Press (May 2002)
	AS	<u>11</u>	Cai, Y., <i>et al.</i> , "Effect of O <sup>6</sup> -Benzylguanine on Nitrogen Mustard-induced Toxicity, Apoptosis, and Mutagenicity in Chinese Hamster Ovary Cells," <i>Mol. Cancer Ther.</i> 1:21-28, American Association for Cancer Research, Inc. (November 2001)
	AT	<u>11</u>	Cornelis, G.R., "Molecular and cell biology aspects of plague," <i>Proc. Natl. Acad. Sci. USA</i> 97:8778-8783, National Academy of Sciences (2000)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>12</u>	Hippenstiel, S., <i>et al.</i> , "Rho protein inactivation induced apoptosis of cultured human endothelial cells," <i>Am. J. Physiol. Lung Cell Mol. Physiol.</i> 283:L830-L838, American Physiological Society (June 2002)
	AS	<u>12</u>	Kemp, K., <i>et al.</i> , "Pneumococcal Infections in Humans Are Associated with Increased Apoptosis and Trafficking of Type 1 Cytokine-Producing T Cells," <i>Infect. Immun.</i> 70:5019-5025, American Society For Microbiology (September 2002)
	AT	<u>12</u>	Koo, H.M., <i>et al.</i> , "Apoptosis and melanogenesis in human melanoma cells induced by anthrax lethal factor inactivation of mitogen-activated protein kinase kinase," <i>Proc. Natl. Acad. Sci. USA</i> 99:3052-3057, National Academy of Sciences (March 2002)

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**U.S. PATENT DOCUMENTS**

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FORM PTO-1449

ATTY. DOCKET NO.  
1735.0760002/RWE/RASAPPLICATION NO.  
10/510,104 (U.S. Nat'l Phase of  
PCT/US03/10645, filed April 7, 2003)INFORMATION DISCLOSURE STATEMENTAPPLICANT(S)  
Cai *et al.*35 U.S.C. §3 71 DATE  
October 5, 2004ART UNIT  
To be assigned

INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>13</u>	Mills, S.D., <i>et al.</i> , "Yersinia enterocolitica induces apoptosis in macrophages by a process requiring functional type III secretion and translocation mechanisms and involving YopP, presumably acting as an effector protein," <i>Proc. Natl. Acad. Sci. USA</i> 94:12638-12643, National Academy of Sciences (1997)
	AS	<u>13</u>	Paris, F., <i>et al.</i> , "Endothelial Apoptosis as the Primary Lesion Initiating Intestinal Radiation Damage in Mice," <i>Science</i> 293:293-297, American Association for the Advancement of Science (July 2001)
	AT	<u>13</u>	Prabhakaran, K., <i>et al.</i> , "Cyanide Induces Different Modes of Death in Cortical and Mesencephalon Cells," <i>J. Pharmacol. Exp. Ther.</i> 303:510-519, American Society for Pharmacology and Experimental Therapeutics (November 2002)

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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>14</u>	Sheikh, M.S., <i>et al.</i> , "Ultraviolet-irradiation-induced apoptosis is mediated via ligand independent activation of tumor necrosis factor receptor 1," <i>Oncogene</i> 17:2555-2563, Nature Publishing Group (1998)
	AS	<u>14</u>	International Search Report for International Application No. PCT/US03/10645, United States Patent and Trademark Office, mailed on January 14, 2004
	AT		

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